State of Utah
Administrative Rule Analysis

NOTICE OF PROPOSED RULE OR CHANGE

The agency identified below in box 1 provides notice of proposed rule or change pursuant to Utah Code Subsections 63-46a-4(2) and (4). Please address questions regarding information on this notice to the agency. The full text of all rule filings is published in the *Utah State Bulletin* unless excluded because of space constraints. The full text of all rule filings may also be inspected at the Division of Administrative Rules.

State of Utah ***Division of Administrative Rules (DAR)*** ***4120 State Office Building; 450 North Main*** ***PO Box 141007*** ***Salt Lake City, UT 84114-1007*** ***Phone: (801) 538-3218, FAX: (801) 538-1773*** ***State E-mail: asdomain.asitmain.rules***	**DAR file no.:** **Utah Admin. Code ref. (R no.): R156-37** **Date filed:** **Time filed:** **Received by:**

1. Department: **Commerce**
Agency: **Occupational and Professional Licensing**
Room no., building: **Heber M. Wells Building - 4th Floor**
Street address: **160 East 300 South**
Mailing address: **PO Box 146741**
City, state ZIP: **Salt Lake City UT 84114-6741**
Contact person: **Laura Poe**
Telephone: **(801) 530-6789**
FAX: **(801) 530-6511**
Internet E-mail: **lpoe@utah.gov**

(Interested persons may inspect this filing at the above address or at DAR between 8:00 a.m. and 5:00 p.m. on business days.)

2. Title of rule or section (catchline):

Utah Controlled Substances Act Rules

3. Type of notice:

Proposed rules		**New**	**X**	**Amendment**		**Repeal**
		Repeal and reenact				
Other rule types		**Change in proposed rule**				**)**

4. Purpose of the rule or reason for the change:

The Division needs to clarify two subsections in the existing rule and add amendments to allow an individual who does not have a primary license to obtain a Utah controlled substance license in order to receive and store controlled substances.

5. This rule or change is a response to comments by the Administrative Rules Review Committee.		**Yes**	**X**	**No**

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6. Summary of the rule or change:

Section 102-Definitions: Added a definition for "principle place of business or professional practice" so practitioners understand when more than one controlled substance license is needed. Section 302-Application Requirements: Additions were made to allow individuals who are employed by the government to perform animal capture to obtain a controlled substance license without a primary license. Addition also allows controlled substance licensure for ambulance companies so that they may obtain and store controlled substances for use in ambulances. Section 603-Restrictions Upon the Prescription, Dispensing and Administration of Controlled Substances: Amendments are made to paragraph (4) to clarify that a prescription written with a dispensing date in the future may be filled within 10 days of the date so the customers in rural areas or who utilize mail order pharmacies may obtain their prescriptions in a timely manner.

7. Aggregate anticipated cost or savings to:

State budget:	**The Division will incur minimal costs, less than $50.00, to reprint this rule once the proposed amendment are made effective. Any costs incurred will be absorbed in the current Division budget.**
Local government:	**Proposed amendments do not affect local government**
Other persons:	**By clarifying the principle place of business to mean any location where controlled substances are received or stored, some practitioners may not need to obtain as many controlled substance licenses as they have in the past, thus resulting in a savings of a $90.00 application fee and a $50.00 renewal fee every two years. Also, in the past the Division has required individuals to obtain a research pharmacy license in order to obtain a controlled substance license; however, these proposed amendments will now allow the controlled substance license without primary licensure thus saving a $100.00 application fee and a $50.00 renewal fee every two years. The Division is unable to determine an aggregate savings amount since the number of people affected by these proposed amendments is unknown.**

8. Compliance costs for affected persons **("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an agency):**

By clarifying the principle place of business to mean any location where controlled substances are received or stored, some practitioners may not need to obtain as many controlled substance licenses as they have in the past, thus resulting in a savings of a $90.00 application fee and a $50.00 renewal fee every two years. Also, in the past the Division has required individuals to obtain a research pharmacy license in order to obtain a controlled substance license; however, these proposed amendments will now allow the controlled substance license without primary licensure thus saving a $100.00 application fee and a $50.00 renewal fee every two years.

9. Comments by the department head on the fiscal impact the rule may have on businesses:

The proposed rule changes do not appear to pose any negative fiscal impact to businesses, and may in fact result in a positive fiscal impact to certain regulated individuals and businesses who will no longer need a primary license in addition to a controlled substance license. Ted Boyer, Executive Director

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10. This rule or change is authorized or mandated by state law, and implements or interprets the following state and federal laws.				
State code or constitution citations (required):	**Subsections 58-1-106(1) and 58-37-6(1)**			
Federal citations (optional):				
11. This rule or change adds or updates an incorporated reference (submit a copy to DAR):		**Yes**	**X**	**No**
Reference title and date of issue or edition:				

12. The public may submit written or oral comments to the agency identified in box 1. **(The public may also request a hearing by submitting a written request to the agency. The agency is required to hold a hearing if it receives requests from ten interested persons or from an association having not fewer than ten members. Additionally, the request must be received by the agency not more than 15 days after the publication of this rule in the *Utah State Bulletin*. See Section 63-46a-5 and Rule R15-1 for more information.)**

Comments wi	**08/14/2002**		
A public h			

13. This rule or change may become effective on (mm/dd/yyyy):	**08/15/2002**	

14. Indexing information - keywords (maximum of four, in lower case):

controlled substances, licensing

15. Indexing information - affected industries (two-digit SIC codes):

n/a

16. Attach a WordPerfect document containing the text of this rule or change (filename):	**R156-37.pro**

To the agency: Information requested on this form is required by Sections 63-46a-4, 5, 6, and 10. Incomplete forms may be returned to the agency for completion, possibly delaying publication in the *Utah State Bulletin*, and delaying the first possible effective date.

AGENCY AUTHORIZATION

Agency head or designee, and title:	**J. Craig Jackson, Director**	**Date (mm/dd/yyyy):**	**06/27/2002**

R156. Commerce, Occupational and Professional Licensing.
R156-37. Utah Controlled Substances Act Rules.
R156-37-102. Definitions.

In addition to the definitions in Title 58, Chapters 1 and 37, as used in Title 58, Chapters 1 and 37, or these rules:

(1) "DEA" means the Drug Enforcement Administration of the United States Department of Justice.

(2) "NABP" means the National Association of Boards of Pharmacy.

(3) "Principle place of business or professional practice", as used in Subsection 58-37-6(2)(e), means any location where controlled substances are received or stored.

(4) "Schedule II controlled stimulant" means any material, compound, mixture or preparation listed in Subsection 58-37-4(2)(b)(iii).

([~~4~~]5) "Unprofessional conduct", as defined in Title 58 is further defined in accordance with Subsections 58-1-203(5) and 58-37-6(1)(a), in Section R156-37-502.

R156-37-302. Qualifications for Licensure - Application Requirements.

(1) An applicant for a controlled substance license shall:

(a) submit an application in a form as prescribed by the division; and

(b) shall pay the required fee as established by the division under the provisions of Section 63-38-3.2.

(2) Any person seeking a controlled substance license shall:

(a) be currently licensed by the state in the appropriate professional license classification as listed in R156-37-301 and shall maintain that license classification as current at all times while holding a controlled substance license; or

(b) be engaged in the following activities which require the administration of a controlled substance but do not require licensure under Subsection (a):

(i) animal capture for transport or relocation as an employee or under contract with a state or federal government agency;

(ii) providing emergency services to an injured or ill person by an ambulance service; or

(iii) other activity approved by the Division in collaboration with the appropriate board.

(3) The division and the reviewing board may request from the applicant information which is reasonable and necessary to permit an evaluation of the applicant's:

(a) qualifications to engage in practice with controlled substances; and

(b) the public interest in the issuance of a controlled substance license to the applicant.

(4) To determine if an applicant is qualified for licensure, the division may assign the application to a qualified and appropriate licensing board for review and recommendation to the division with respect to issuance of a license.

R156-37-603. Restrictions Upon the Prescription, Dispensing and Administration of Controlled Substances.

(1) A practitioner may prescribe or administer the Schedule II controlled substance cocaine hydrochloride only as a topical anesthetic for mucous membranes in surgical situations in which it is properly indicated and as local anesthetic for the repair of facial and pediatric lacerations when the controlled substance is mixed and dispensed by a registered pharmacist in the proper formulation and dosage.

(2) A practitioner shall not prescribe or administer a controlled substance without taking into account the drug's potential for abuse, the possibility the drug may lead to dependence, the possibility the patient will obtain the drug for a nontherapeutic use or to distribute to others, and the possibility of an illicit market for the drug.

(3) When writing a prescription for a controlled substance, each prescription shall contain only one controlled substance per prescription form and no other legend drug or prescription item shall be included on that form.

(4) [~~A prescription for a Schedule II controlled substance shall not be written for a quantity greater than medically necessary and in no case in quantities greater than a 30 day supply~~]When issuing more than one prescription at the same time for the same Schedule II controlled substance in accordance with Subsection 58-37-6(7)(f)(v), the restriction in Subsection (D) therein, that unless the practitioner determines there is a valid medical reason to the contrary, the date for dispensing the second or third prescription may not be fewer than 30 days from the dispensing date of the previous prescription, is clarified by determining that a valid medical reason to the contrary including dispensing a second or third no more than 10 days earlier, to allow for receipt of the prescription before the previous prescription runs out.

(5) If a practitioner fails to document his intentions relative to refills of controlled substances in Schedules III through V on a prescription form, it shall

mean no refills are authorized. No refill is permitted on a prescription for a Schedule II controlled substance.

(6) Refills of controlled substance prescriptions shall be permitted for the period from the original date of the prescription as follows:

(a) Schedules III and IV for six months from the original date of the prescription; and

(b) Schedule V for one year from the original date of the prescription.

(7) No refill may be dispensed until such time has passed since the date of the last dispensing that 80% of the medication in the previous dispensing should have been consumed if taken according to the prescriber's instruction.

(8) No prescription for a controlled substance shall be issued or dispensed without specific instructions from the prescriber on how and when the drug is to be used.

(9) Refills after expiration of the original prescription term requires the issuance of a new prescription by the prescribing practitioner.

(10) Each prescription for a controlled substance and the number of refills authorized shall be documented in the patient records by the prescribing practitioner.

(11) A practitioner shall not prescribe or administer a Schedule II controlled stimulant for any purpose except:

(a) the treatment of narcolepsy as confirmed by neurological evaluation;

(b) the treatment of abnormal behavioral syndrome, attention deficit disorder, hyperkinetic syndrome, or related disorders;

(c) the treatment of drug-induced brain dysfunction;

(d) the differential diagnostic psychiatric evaluation of depression;

(e) the treatment of depression shown to be refractory to other therapeutic modalities, including pharmacologic approaches, such as tricyclic antidepressants or MAO inhibitors;

(f) in the terminal stages of disease, as adjunctive therapy in the treatment of chronic severe pain or chronic severe pain accompanied by depression;

(g) the clinical investigation of the effects of the drugs, in which case the practitioner shall submit to the division a written investigative protocol for its review and approval before the investigation has begun. The investigation shall be conducted in strict compliance with the investigative protocol, and the practitioner shall, within 60 days following the conclusion of the

investigation, submit to the division a written report detailing the findings and conclusions of the investigation; or

(h) in treatment of depression associated with medical illness after due consideration of other therapeutic modalities.

(12) A practitioner may prescribe, dispense or administer a Schedule II controlled stimulant when properly indicated for any purpose listed in Subsection (11), provided that all of the following conditions are met:

(a) before initiating treatment utilizing a Schedule II controlled stimulant, the practitioner obtains an appropriate history and physical examination, and rules out the existence of any recognized contraindications to the use of the controlled substance to be utilized;

(b) the practitioner shall not prescribe, dispense or administer any Schedule II controlled stimulant when he knows or has reason to believe that a recognized contraindication to its use exists;

(c) the practitioner shall not prescribe, dispense or administer any Schedule II controlled stimulant in the treatment of a patient who he knows or should know is pregnant; and

(d) the practitioner shall not initiate or shall discontinue prescribing, dispensing or administering all Schedule II controlled stimulants immediately upon ascertaining or having reason to believe that the patient has consumed or disposed of any controlled stimulant other than in compliance with the treating practitioner's directions.

KEY: controlled substances, licensing
[~~May 19, 1998~~]2002 **58-1-106(1)**
Notice of Continuation May 9, 2002 **58-37-6(1)**